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| EXAMINER |
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CHANNAVAJJALA, LAKSHMI SARADA

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1615

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11/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/783,151

Applicant(s)

OBLONG ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 10-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>8-23-04, 9-30-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of response to Restriction requirement dated 8-23-07 is acknowledged.

Claims 1-24 are pending in the instant application.

Election/Restrictions

1. Applicant's election of Group I (claims 1-9) in the reply filed on 8-23-07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants further elected the following species:

1. Species 1 (claim 1)- Agmatine where $R1=R2=R3=R4=H$, $A=N$,
 $B=D=R5=R6=R7=R8=R9= \text{nil}$; $C=NH_2$ and $n=4$
2. Species 2- (Claim 2) hexamidine
3. Species 3- (Claim 3)- BHT and
4. Species 4- (Claims 7 and 8) – vitamin B3 compounds.

After careful consideration, the examiner has withdrawn the election requirement of species for first, second and third skin care active substances. The election of species requirement only for the ultimate species of Agmatine has been maintained.

While the response dated 8-23-07 states that claims 1-9 read on the elected species and claims 10-23 are canceled, applicants did submit complete set of claims showing the cancellation of claims.

Accordingly, withdrawn claims 10-23 are considered pending.

The following rejection applies to claims 1-9:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4 and 7-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,716,441 (US '441) in view of WO 03/092668 (WO) and US 6149896 (US 896).

The claims of US '441 are directed to an article comprising a release composition, which comprises at least one skin care active selected from the group consisting of hexamidine, vitamin B3, chitosan, phytic acid, panthenol, niacinamide, EDTA, triacetin, phenylsulfonfyl fluoride and mixtures thereof. US '441 does not teach Agmatine and BHT of the instant claims.

WO teaches (submitted on PTO-1449 by applicants, only abstract) the use of Agmatine and/or their derivatives for topical application in skin care and cosmetics.

US 896 teach cosmetic compositions for enhancing the repair of damage caused by exposure to sunlight. The composition of '896 is comprised of niacinamide (Vitamin B3), BHT, propyl gallate, NDGA and other skin care actives (see col. 3-4 and examples). All of the above references are directed to compositions providing skin care such as preventing the damage or enhancing the repair caused by the damage of UV radiation and thus constitutes analogous art. In this regard, instant claims do not recite any specific activity. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include suitable amounts of Agmatine (WO) and the skin care actives such as BHT, gallate etc (of US 896) in the composition of US 441 with an expectation to achieve the desired skin care.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 7-9 rejected under 35 U.S.C. 103(a) as being unpatentable over US 6149896 in view of US 4,507, 321 or in view of WO 03/092668

US 896 teach cosmetic compositions for enhancing the repair of damage caused by exposure to sunlight, wherein the damage includes skin burns and skin cancer. The composition of '896 is comprised of niacinamide (Vitamin B3), BHT, propyl gallate, NDGA and other skin care actives (see col. 3-4 and examples). US 896 fail to teach the claimed agmatine.

WO teaches (submitted on PTO-1449 by applicants, only abstract) the use of Agmatine and/or their derivatives for topical application in skin care and cosmetics.

US 321 teach epithelial growth regulating compositions, useful for wound healing, and treating burns, eczema, senile pruritis etc comprising polyamine compounds such as agmatine (abstract, col. 1, summary, col. 2, L 63 through col. 4, L 4 and col. 4, L 34-63, **col. 6, I 20-33 and L 64-68**). '321 teach preparing polyamine compositions in the form of ointments, creams, lotions etc., for topical applications (examples and col. 3, L 57-65).

All of the above references are directed to compositions providing skin care such as preventing the damage or enhancing the repair caused by the damage of UV radiation and thus constitutes analogous art. In this regard, instant claims do not recite any specific activity. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include suitable amounts of Agmatine (WO or of US 321) in the skin care composition of US 896 containing actives such as BHT, gallate etc with an expectation to treat the UV damaged skin and also provide treatment for skin burn and a cosmetic care because US 321 suggests that the compositions containing polyamines such as agmatine provide relief from burn and WO

teaches agmatine for cosmetic use. With respect to the claimed amounts, US 321 suggests 0.05 micromoles to 10 millimoles (examples) or 0.005% to 5% (claims) of polyamines and US 896 suggests 0.02% of niacinamide and 0.01% BHT (examples), all of which are within the claimed range.

4. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6149896 in view of US 4,507, 321 or in view of WO 03/092668 as applied to claims 1-4 and 7-9 above, and further in view of either one of US 2003/0190337 (PGPUB) or US 5709847 (US 847).

US 896, WO and US 321, discussed above, fail to teach the claimed green tea extracts and cetylpyridinium.

PGPUB 337 teaches a composition for the regulation of skin conditions ([0025]) comprising active agents such as peptides, phytosterol, (0044), vitamin B3 compounds (0134) antioxidants such as aminoguanidines, tea extracts, etc ([0148], see examples VII-XI). PGPUB 337 fail to teach cetylpyridinium. However, the reference teaches inclusion of several cationic emulsifiers ([0101-0105]).

847 teach compositions radical scavenging and anti-inflammatory agents and also for preventing the damage of skin by UV radiation damage comprising active agents such as vitamin e, aminoguanidines, urea, etc (col. 4 and examples). '847 teach the compositions contain emulsifiers such as cationic, anionic and nonionic emulsifiers and teach cetylpyridinium as a suitable cationic emulsifier (col. 12, L 32-38).

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include effective amounts of the skin care actives such as tea extracts, phytosterol etc of PG PUB 337 of '847 in the composition of US 896 because all of the references are directed to skincare compositions, particularly for reducing the damage caused by UV radiation and suggests active agents as anti-oxidants scavenging free radicals, thus providing enhanced protection from UV damage. Further, a skilled artisan would have added cetylpyridinium chloride of '847 as cationic emulsifier because the reference teaches cetylpyridinium as a suitable emulsifier in preparing the emulsions

5. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,716,441 (US '441) in view of WO 03/092668 (WO) and US 6149896 (US 896).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject

matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

US 441 teach a skincare composition comprising at least one skin care active selected from the group consisting of hexamidine, vitamin B3, chitosan, phytic acid, panthenol, niacinamide, EDTA, triacetin, phenylsulfonyl fluoride and mixtures thereof (col. 5, L 17-65) and includes the claimed hexamidine, vitamin B3 niacinamide etc. US '441 does not teach Agmatine and BHT of the instant claims.

WO teaches (submitted on PTO-1449 by applicants, only abstract) the use of Agmatine and/or their derivatives for topical application in skin care and cosmetics.

US 896 teach cosmetic compositions for enhancing the repair of damage caused by exposure to sunlight. The composition of '896 is comprised of niacinamide (Vitamin B3), BHT, propyl gallate, NDGA and other skin care actives (see col. 3-4 and examples). All of the above references are directed to compositions providing skin care such as preventing the damage or enhancing the repair caused by the damage of UV radiation and thus constitutes analogous art. In this regard, instant claims do not recite any specific activity. Accordingly, it would have been obvious for one of an ordinary skill

in the art at the time of the instant invention to include suitable amounts of Agmatine (WO) and the skin care actives such as BHT, gallate etc (of US 896) in the composition of US 441 with an expectation to achieve the desired skin care.

6. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being obvious over WO 01/443717 (WO '717 claims priority to the application of U.S. Patent No. 6,716,441 and has the same disclosure as US '441) in view of WO 03/092668 (WO) and US 6149896 (US 896).

WO '717 also teaches a skincare composition comprising at least one skin care active selected from the group consisting of hexamidine, vitamin B3, chitosan, phytic acid, panthenol, niacinamide, EDTA, triacetin, phenylsulfonyl fluoride and mixtures thereof (page 6) and includes the claimed hexamidine, vitamin B3 niacinamide etc. WO '717 does not teach Agmatine and BHT of the instant claims.

WO teaches (submitted on PTO-1449 by applicants, only abstract) the use of Agmatine and/or their derivatives for topical application in skin care and cosmetics.

US 896 teach cosmetic compositions for enhancing the repair of damage caused by exposure to sunlight. The composition of '896 is comprised of niacinamide (Vitamin B3), BHT, propyl gallate, NDGA and other skin care actives (see col. 3-4 and examples). All of the above references are directed to compositions providing skin care such as preventing the damage or enhancing the repair caused by the damage of UV radiation and thus constitutes analogous art. In this regard, instant claims do not recite

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any specific activity. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include suitable amounts of Agmatine (WO) and the skin care actives such as BHT, gallate etc (of US 896) in the composition of WO 717 with an expectation to achieve the desired skin care.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615

November 1, 2007

A handwritten signature in black ink, appearing to read "Lakshmi S. Channavaajjala", written over a horizontal line.

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER